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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,457	ZHAO ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,37,39,42-44,46,48 and 51-123* is/are pending in the application.

4a) Of the above claim(s) *1-34 and 52-121* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35, 37, 39, 42-44, 46, 48, 51, 122, and 123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response of 11/21/08 are entered.

Claims 35, 37, 39, 44, 46, and 48 are amended.

Claims 36, 38, 40, 41, 45, 47, 49, and 50 are cancelled.

Claims 122 and 123 are newly presented.

Claims 1-35, 37, 39, 42-44, 46, 48, and 51-123 are presently pending.

Election/Restrictions

Claims 1-34 and 52-121 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/17/08.

Hence, Claims 35, 37, 39, 42-44, 46, 48, 51, 122, and 123 are presently considered.

Claim Status, Cancelled Claims

In light of the cancellation of Claims 36, 38, 40, 41, 45, 47, 49, and 50, the rejections and/or objections to such claims are rendered moot, and thus, are withdrawn.

Claim Objections

The objections to Claims 35, 37, 39, 42-44, 46, 48, 51 are withdrawn.

To wit, the independent claims now make clear that cell death is a characteristic of the disease, or the cause of cell death.

Claim Rejections - 35 USC § 112 – written description

Claims 35, 37, 39, 42-44, 46, 48, 51, 122, and 123 remain and/or are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Argument - written description, modified forms of ATF6

Applicant's argument of 11/21/08 have been fully considered but are not found persuasive.

Applicant argues that the independent claims have been limited to the specific forms of ATF6, and thus, because the specification also lists such, there is sufficient written description to understand Applicant possessed such (pp. 20-21, paragraph bridging).

Such is not persuasive. As has been stated, the proteins are required by the claims to inhibit cell death and treat disorders through their function in inhibiting cell death. Hence, not only is the mere statement of a generic structure required, the patentable function of the protein must also have written description directly understood to be linked to such structure. As shown in the rejection, "without any demonstration of the inhibition of cell death, either in the Art, or in Applicant's disclosure, the Artisan certainly does not know which regions are required for the ATF6 are required, and further whether any particular modification would have ramifications on the 3 dimensional stereochemistry such that it would preclude cell death inhibition" (OA of

7/30/08, written description rejection). Hence, for any particular generic form or fragment of the ATF6, or for any fusion of ATF6, nothing would be found to be possessed.

Lastly, Claims 39 and 48 demonstrate Applicant's complete intent to claim even more than the broad claim would at first appear to claim and to encompass that which is argued to have been removed from the claims. (E.g. Ubiquitination would seem to target the ATF for destruction, rather than activate UPR.) Moreover, the reasoning is provided that these forms are not possessed, and Applicant's arguments that they specifically exclude these forms border on the frivolous.

Claim Rejections - 35 USC § 112 – enablement, complete lack

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 37, 39, 42-44, 46, 48, 51, 122, and 123 remain and/or are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Argument – enablement, complete lack

Applicant's argument of 11/21/08 have been fully considered but are not found persuasive.

Applicant argues that the claims have been amended to limit the disease treatment to be associated with abnormal precipitation/accumulation of proteins, and cell death that would otherwise occur due to undesired accumulation of proteins (p. 21, last paragraph).

Such is not persuasive. As has been stated, Applicant's own evidence is the art-recognized evidence that ATF6 is associated with the unfolded protein response. However, as has also been stated " those mechanisms that do involve the unfolded protein response similarly would be expected to unaffected … Similarly, even within the UPR, other mechanisms are recognized to be involved (e.g., Id.), and hence, simply by affecting a single pathway in the complicated interplay of mechanisms in such cells would similarly not be reasonably expected to work without evidence, or a better understanding of the types of cell death, the mechanisms of each form of cell death, as well as, the interplay of the various mechanisms. Therefore, even if Applicant were to demonstrate a single form of inhibition of cell death, it would appear to be limited to that specific form of cell death which is being inhibited in that particular type of cell". In essence, mere association is not enough to enable the claims. If the UPR is not activated because a protein downstream of ATF6 is not working, it doesn't matter if ATF6 is present. If the UPR is not activated because there is a dominant-negative form of ATF6 present, it doesn't matter if more ATF6 is presented. If the cell death complex interplay is not understood, the influence of this single player, even if it corrects the problems with the cell's ATF6, cannot be reasonably predicted. Moreover, Applicant fails to demonstrate even one example of inhibition of cell death. How can it be more than an invitation to experiment and determine if the methods work for any particular disorder or cell type? Sill further, administration methods are not

addressedby Applicant. The experimentation required to make such reasonably predictable is simply undue as it amounts to inventing the claimed subject matter for Applicant.

Applicant argues that paragraph 0119 (of the Application publication) demonstrates that they discovered that cell death is prevented by such administrations (pp. 22-23, paragraph bridging).

Such is not persuasive. Applicant has averred, but has not demonstrated any such discovery. Hence, it is not "discovered" such that it could be reasonably predicted for any cell.

Lastly, Claims 39 and 48 demonstrate Applicant's complete intent to claim even more than the broad claim would at first appear to claim and to encompass that which is argued to have been removed from the claims. (E.g. Ubiquitination would seem to target the ATF for destruction, rather than activate UPR.) Moreover, the reasoning has been provided that these forms are not enabled, and Applicant's arguments that they specifically exclude these forms border on the frivolous.

Even though facing a complete lack of enablement, because the Artisan would have other reasons to perform the same method steps, certain claims are rejected for being obvious.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 44, 46, 48, and 51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over, alternatively, U.S. Patent No. 6,635,751 or WO 2000/29429, each to Haze, et al.

Because the disclosures are the same, the patent is referred to only.

Haze teaches the administration of ATF6 to a cell, via administration of a plasmid encoding ATF6 (e.g., EXAMPLE 2). Further soluble forms are also taught (e.g., col. 11). Still further several other cell types, including HeLa cells were used to express ATF6 from a plasmid (EXAMPLES).

With regard to Claim 46, the ATF6 is human ATF6 (EXAMPLE 3).

With regard to Claims 48, mutants comprising, *inter alia*, deletions can be used (e.g., col. 11, paragraph 4), which can obviously be made by covalent modification of the full length protein. Further the deletions would be instantly-obvious to the Artisan that proteolytic processing may be used. Such techniques are well known in the Art (Official Notice).

With regard to Claim 51, water and salts would necessarily be present to allow administration of a functional protein (Official Notice).

As it was well known in the Art that proteins can be administered to cells by injection (Official Notice), it would have been obvious to administer the various ATF6 proteins to cells, instead of using a plasmid to express the protein. The Artisan would have done so to affect the similar tests. Moreover, the Artisan would have had a reasonable expectation of success, as the protein is placed into the cell, which is all that is required.

Lastly, as no demonstration of cell death is provided, it is presumed that any death is prevented.

Response to Argument – 35 USC 103(a), Haze, et al. references

Applicant's argument of 11/21/08 has been fully considered but is not found persuasive.

Applicant argues that the yeast cells of Haze, et al. are not a population "in need thereof" (p. 22, last paragraph).

Such is not persuasive. The cells "in need thereof" are at the opinion of the Artisan, not Applicant's opinion. Further, the method claims that cell death that would otherwise occur from an undesired accumulation of proteins is prevented versus absence of ATF6, and hence, does not even require that the cells are accumulating protein, much less the precipitated protein which induces the UPR. Applicant's claims are so broad therefore, that the claims are still rejected. Still further, Example 5 demonstrates HeLa cells similarly expressing ATF6. Hence, similar arguments to Yeast can be made for HeLa cells.

Applicant argues that the cells of Haze are not prevented from cell death would otherwise occur from an undesired accumulation of proteins (p. 22, last paragraph).

Such is not persuasive. Applicant's claims do not require that the cells accumulate protein, much less the precipitate that causes UPR. Moreover, there is no evidence, and Applicant's claims are not limited to exclude the cells of Haze. Further, absent reason to believe otherwise, if there were an accumulation of proteins, the ATF6 used by Haze in those cells would prevent cell death.

Applicant broadly avers that the Examiner has failed to provide any basis of rejection (pp. 22-23, paragraph bridging), and hence, the rejection should be withdrawn (Id.).

Such is not persuasive. It is suggested that Applicant read the substance of the rejection next time.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633